



Attorney's Docket No.: 17170-002002 (25835-4001B)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gerardo Castillo et al.

Serial No. : 10/762,444

Filed : January 21, 2004

Title : POLYHYDROXYLATED AROMATIC COMPOUNDS FOR THE
TREATMENT OF AMYLODOSIS AND ALPHA-SYNUCLEIN FIBRIL
DISEASES

Art Unit : Unknown

Examiner : Unknown

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Transmitted herewith are an Information Disclosure Statement and Forms PTO-1449 6) pages for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Dale L. Rieger
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I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

April 8, 2004

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Kelly M. Fischer

Typed or Printed Name of Person Signing Certificate



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gerardo Castillo et al. Art Unit : Unknown
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Commissioner for Patents
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Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
IN ACCORDANCE WITH 37 C.F.R. 1.97-1.98

Dear Sir:

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application a fee is not required. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (6 pages) are provided herewith in connection with the above-captioned application. In accordance with 37 C.F.R. §1.98(d), copies of the references listed on the Form PTO-1449 are not provided herewith as they have been previously provided in connection with U.S. Serial Nos. 09/748,748, which are relied upon for an earlier filing date in accordance with 35 U.S.C. §120.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

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The documents cited on the Forms PTO-1449 are in the English language, with the exception of Items X, AC, AF, and CD. Items X and AC (Japanese patent Nos. JP 10245342 and JP 1-151514 respectively) are in in the Japanese language and were supplied with Derwent English Abstracts (Items BB and BA respectively). Item AF (International Patent Application Publication No. WO 98/09653) is in the French language and was supplied with an English language equivalent US patent 6,297,281 (Item R). Item CD (Article by Lewy (1912)) is in the German language and was supplied with a Certified English language translation (Item AV). Hence, in accordance with the requirements of 37 C.F.R. 1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following pending U.S applications that have one or more common inventors and/or are commonly owned:

U.S.S.N.(App. no.)	Filing Date	Docket No.
09/748,748	12/26/00	17170-002001 (HEWM; 25835-4001)
10/452,851	05/30/03	17170-003001 (HEWM; 25835-4002)
10/684,178	10/10/03	17170-004001 (HEWM; 25835-4003)
10/384,172	03/05/03	
09/036,492	03/06/98	
09/079,829	03/15/98	
09//497,628	02/03/00	
09/296,481	10/02/98	
09/525,787	03/15/00	

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(b) exists.

Applicant : Gerardo Castillo et al.
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Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Date: 4/6/04


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Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17170-002002	Application No. 10/762,444
List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b))		Applicant Gerardo Castillo et al.		
		Filing Date January 21, 2004	Group Art Unit Unknown	

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	A	2002/0111309	08/15/02	Castillo et al.	514	12	08/22/01
	B	2002/0168753	11/14/02	Castillo et al.	435	226	11/30/01
	C	2002/0197692	12/26/02	Castillo et al.	435	184	11/02/01
	D	2003/0013648	01/16/03	Castillo et al.	514	12	09/24/01
	E	2003/0017998	01/23/03	Snow et al.	514	27	02/15/02
	F	5,643,562	07/01/97	Kisilevsky et al.	424	78.31	03/15/95
	G	5,681,569	10/28/97	Kuznicki et al.	424	195	11/06/95
	H	5,719,191	02/17/98	Maclean et al.	514	648	02/21/97
	I	5,731,313	03/24/98	Suarato et al.	514	255	07/24/95
	J	5,747,517	05/05/98	Panetta et al.	514	369	09/11/96
	K	5,767,126	06/16/98	Marchbanks	514	297	1018/94
	L	5,869,469	02/09/99	Szarek	514	120	08/18/97
	M	5,958,883	09/28/99	Snow	514	16	06/05/95
	N	5,972,956	10/26/99	Hays et al.	514	297	04/29/98
	O	5,981,168	11/09/99	Reiner	435	4	05/15/98
	P	6,037,327	03/14/00	Castillo et al.	514	23	08/28/99
	Q	6,264,994	07/24/01	Castillo et al.	424	725	12/08/98
	R	6,297,281	10/02/01	De Lassauniere et al.	514	589	03/02/99
	S	6,340,783	01/22/02	Snow	800	12	10/03/96
	T	6,346,280	02/12/02	Castillo et al.	424	725	11/24/98
	U	6,432,636	08/13/02	Maresh et al.	435	6	08/26/97
	V	6,563,016	05/13/02	Snow et al.	800	12	03/27/00

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID <input checked="" type="checkbox"/>	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
	W <input checked="" type="checkbox"/>	00/12102	03/09/00	PCT			
	X <input checked="" type="checkbox"/>	10245342	09/14/98	JP			X+

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Date Considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
	Y	01/49281	07/12/01	PCT				
	Z	01/49307	07/12/01	PCT				
	AA	0 659 418	12/19/94	EP				
	AB	1 014 996	05/28/03	EP				
	AC	1-151514	06/14/89	JP				X+
	AD	97/46664	12/11/97	PCT				
	AE	98/08381	03/05/98	PCT				
	AF	98/09653	03/12/98	PCT				X+
	AG	98/24646	06/11/98	PCT				
	AH	98/34646	08/13/98	PCT				
	AI	98/39653	09/11/98	PCT				
	AJ	98/51302	11/19/98	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AK	Arai et al, "Argyrophilic glial inclusions in the midbrain of patients with Parkinson's disease and diffuse Lewy body disease are immunopositive for NACP/α-synuclein," <i>Neurosc. Lett.</i> 259:83-86 (1999)
	AL	Barner et al., "Donepezil Use in Alzheimer Disease", <i>Ann. Pharmacotherapy</i> , 32:70-77 (1998)
	AM	Benson et al., "Serum Amyloid A Protein In Amyloidosis, Rheumatic, And Neoplastic Diseases", <i>Arth. Rheum.</i> , 22:36-42 (1979)
	AN	Castillo et al. "Sulfate content and specific glycosaminoglycan backbone of perlecan are critical of perlecan's enhancement of islet amyloid polypeptide (Amylin) Fibril formation." <i>Diabetes</i> , 47: 612-620, (1998)
	AO	Castillo et al., "Laminin inhibition of beta-amyloid protein (A beta) fibrillogenesis and identification of an A beta binding site localized to the globular domain repeat on the laminin a chain", <i>J. Neurosci. Res.</i> , 62(3):451-462 (2000)
	AP	Castillo et al., "Novel purification and detailed characterization of perlecan isolated from the Engelbreth-Holm-Swarm tumor for use in an animal model of fibrillar A beta amyloid persistence in brain", <i>J. Biochem.</i> , 120(2):433-444 (1996)
	AQ	Castillo et al., "Perlecan binds to the beta-amyloid proteins (A beta) of Alzheimer's disease, accelerates A beta fibril formation, and maintains A beta fibril stability", <i>J. Neurochem.</i> , 69(6):2452-2465 (1997)

Examiner Signature	Date Considered
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		Filing Date January 21, 2004	Group Art Unit Unknown	

Other Documents (include Author, Title, Date, and Place of Publication)

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	AR*	Castillo et al., "Structure and metabolism of multiple heparan sulphate proteoglycans synthesized by the isolated rat glomerulus", <i>Biochem. Biophys. Acta</i> , 1136(2):119-128 (1992)
	AS*	Castillo et al., "Subunit structure of bovine ESF (extracellular-matrix stabilizing factor(s)). A chondroitin sulfate proteoglycan with homology to human I alpha i (inter-alp trypsin inhibitors)", <i>FEBS Lett.</i> , 318(3):292-296 (1993)
	AT*	Castillo et al., "Sulfate content and specific glycosaminoglycan backbone of perlecan are critical for perlecan's enhancement of islet amyloid polypeptide (amylin) fibril formation", <i>Diabetes</i> , 47(4):612-620 (1998)
	AU*	Castillo et al., "The sulfate moieties of glycosaminoglycans are critical for the enhancement beta-amyloid protein fibril formation", <i>J. Neurochem.</i> , 72(4):1681-1687 (1999)
	AV*	Certified English Translation of Lewy in Handbuch der Neurologie, Lewandowski, Ed., Springer, Berlin, pp. 920-933, 1912
	AW*	Conway et al., "Accelerated <i>in vitro</i> fibril formation by a mutant α -synuclein linked to early-onset Parkinson disease," <i>Nature Med.</i> 4:1318-1320, (1998)
	AX*	Cooper et al. "Purification and characterization of a peptide from amyloid-rich pancreases of type 2 diabetic patients." <i>Proc. Natl. Acad. Sci. USA</i> , 84:8629-8632, (1987)
	AY*	Crutcher et al., "Cellular and molecular pathology in Alzheimer's disease", <i>Hippocampus</i> , 3:271-287 (1993)
	AZ*	Cutler et al., "Tacrine in Alzheimer's Disease", <i>N. Engl. J. Med.</i> , 328:808-810 (1993)
	BA*	Derwent abstract for Japanese Patent Application, JP 1151514, published 06/14/89, "Compsn. For treating and preventing nervous diseases – contains carboxylic acid, pref. gallic or pyrogallol-4-carboxylic acid, esp. useful for alzheimers disease,"
	BB*	Derwent WPI Acc. No. 12134240 (citing Japanese Patent 10245342 A), "Agent for reducing the nerve cell toxicity of beta-amyloid protein containing tea polyphenol is new"
	BC*	Flood et al. "Amnestic effects in mice of four synthetic peptides homologous to amyloid B protein from patients wit alzheimer disease." <i>Proc. Natl. Acad. Sci. USA</i> , 88:3363-3366 (1991)
	BD*	Flood et al. "An amyloid β -protein fragment, A β [12-18], equipotently impairs post-training memory processing when injected into different limbic system structures." <i>Brain Research</i> 663:271-276 (1994).
	BE*	Fraser et al., "Conformation and fibrillogenesis of Alzheimer A beta peptides with selected substitution of charged residues", <i>J. Mol. Biol.</i> , 244(1):64-73 (1994)
	BF*	Fukuchi et al., "Increased expression of beta-amyloid protein precursor and microtubule-associated protein tau during the differentiation of murine embryonal carcinoma cells", <i>J. Neurochem.</i> , 58(5):1863-1873 (1992)
	BG*	Games et al. "Alzheimer-type neuropathology in transgenic mice overexpressing V717F B-amyloid precursor protein." <i>Nature</i> , 373: 523-527 (1995)
	BH*	Geyjo et al., "A New Form of Amyloid Protein Associated with Chronic Hemodialysis was Identified as β 2-microglobulin", <i>Biochem. Biophys. Res. Comm.</i> , 129:701-706 (1985)
	BI*	Geyjo et al., " β 2-microglobulin: A new form of amyloid protein associated with chronic hemodialysis", <i>Kidney Int.</i> , 30:385-390 (1986)

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	BJ*	Glenner et al. "Alzheimer's Disease: Initial Report of the Purification and Characterization of a Novel Cerebrovascular Amyloid Protein," <i>Biochemical and Biophysical Research Communications</i> , 120(3): 885-890 (1984)		
	BK*	Grundke-Ibal et al., "Abnormal phosphorylation of the microtubule-associated protein tau in alzheimer cytoskeletal pathology", <i>Proc. Natl. Acad. Sci. USA</i> , 83:4913-4917 (1986)		
	BL*	Haass et al. "The swedish mutation causes early-onset alzheimer's disease by β-secretase cleavage with in the secretory pathway." <i>Nature Medicine</i> 1(12):1291-1296 (1995).		
	BM*	Harada et al., "Human Amyloid Protein: Chemical Variability And Homogeneity", <i>J. Histochem. Cytochem.</i> , 19:1-15 (1971)		
	BN*	Hardy et al., "Framing β-amyloid", <i>Nature Genet.</i> , 1:233-234 (1992)		
	BO*	Harrigan et al. "Beta Amyloid is Neurotoxic in Hippocampal Slice Cultures," <i>The Neurobiology of Aging</i> , 16(5): 779-789, (1995)		
	BP*	Hart et al., "Overproduction of perlecan core protein in cultured cells and transgenic mice", <i>J. Pathol.</i> , 194(2):262-269 (2001)		
	BQ*	Hashimoto et al., "Human recombinant NACP/α-synuclein is aggregated and fibrillated in vitro: Relevance for Lewy body disease," <i>Brain Res.</i> 799:301-306, (1998)		
	BR*	Hertel et al., "Inhibition of the electrostatic interaction between J-amyloid peptide and membranes prevents J-amyloid-induced toxicity," <i>Proc. Natl. Acad. Sci. USA</i> 94: 9412-9416 (1997)		
	BS*	Hsiao et al. "Age-related CNS Disorder and early death in transgenic FVB/N mice overexpressing alzheimer amyloid precursor proteins." <i>Neuron</i> , vol. 15, 1203-1218, Nov., 1995.		
	BT*	Johnson et al., "Biology of Disease. Islet Amyloid Polypeptide: Mechanisms of Amyloidogenesis in the Pancreatic Islets and Potential Roles in Diabetes Mellitus", <i>Lab. Invest.</i> , 66:522-535 (1992)		
	BU*	Johnson et al., "Islet Amyloid, Islet-Amyloid Polypeptide, and Diabetes Mellitus", <i>N. Engl. J. Med.</i> , 321:513-518 (1989)		
	BV*	Jucker et al., "Age-related deposition of glia-associated fibrillar material in brains of C57BL/6 mice", <i>Neuroscience</i> , 60(4):875-889 (1994)		
	BW*	Kamei et al., "Amyloidosis Associated With Juvenile Rheumatoid Arthritis", <i>Acta Path. Jpn.</i> , 32:123-133 (1982)		
	BX*	Kitaguchi et al. "Novel Precursor of Alzheimer's Disease Amyloid Protein Shows Protease Inhibitory Activity," <i>Nature</i> , 331:530-532, (1988)		
	BY*	Klunk et al., "Quantifying Amyloid B-Peptide (AB) Aggregation Using the Congo Red-AB (CR-AB) Spectrophotometric Assay," <i>Analytical Biochemistry</i> , 266:66-76 (1999)		
	BZ*	Kosik et al., "Microtubule-associated protein tau is a major antigenic component of paired helical filaments in Alzheimer disease", <i>Proc. Natl. Acad. Sci. USA</i> , 83:4044-4048 (1986)		
	CA*	Krüger, Rejko et al., "Ala30Pro mutation in the gene encoding α-synuclein in Parkinson's disease," <i>Nature Genet.</i> 18:106-108, (1998)		
	CB*	Lee et al., "A68: A Major Subunit of Paired Helical Filaments and Derivatized Forms of Normal Tau", <i>Science</i> , 251:675-678 (1991)		
	CC*	Levine. "Thioflavine T interaction with synthetic alzheimer's disease B-amyloid peptides: Detection of amyloid aggregation in solution." <i>Protein Science</i> , 2:404-410, (1993)		
	CD*	Lewy in <i>Handbuch der Neurologie</i> , Lewandowski, Ed., Springer, Berlin, pp. 920-933, 1912		

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Other Documents (include Author, Title, Date, and Place of Publication)

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	CE*	Mandybur et al. "Cerebral Amyloid Angiopathy: The Vascular Pathology and Complications," <i>Journal of Neuropathology and Experimental Neurology</i> , 45(1): 79-90, (1986).
	CF*	Maresh et al., "Detection and quantitation of perlecan mRNA levels in Alzheimer's disease a normal aged hippocampus by competitive reverse transcription-polymerase chain reaction", <i>J. Neurochem.</i> , 67(3):1132-1144 (1996)
	CG*	Masters et al. "Amyloid Plaque Core Protein in Alzheimers Disease and Down Syndrome," <i>Proc. Natl. Acad. Sci. USA</i> 82:4245-4249 (1983)
	CH*	McAdam et al., "Association of Amyloidosis with Erythema Nodosum Leprosum Reactions and Recurrent neutrophil Leucocytosis in Leprosy", <i>Lancet</i> , 2:572-573 (1975)
	CI*	Metaxis et al., "Familial Mediterranean fever and amyloidosis", <i>Kidney Int.</i> , 20:676-685 (1981)
	CJ*	Miller et al., "Localization of perlecan (or a perlecan-related macromolecule) to isolated microglia in vitro and to microglia/macrophages following infusion of beta-amyloid protein into rodent hippocampus", <i>Gila</i> , 21(2):228-243 (1997)
	CK*	Murrell et al. "A mutation in the amyloid recursor protein associated with hereditary alzheimer's disease." <i>Science</i> , 254: 97-99 (1991)
	CL*	Nahri et al. "Both familial Parkinson's disease mutations accelerate I-Synuclein aggregation," <i>J. Biol. Chem.</i> 274:9843-9846 (1999)
	CM*	Naiki et al. "Kinetic analysis of amyloid Fibril polymerization <i>in vitro</i> ." <i>Laboratory Investigation</i> , 65(1):104-110, (1991)
	CN*	Naiki, H. and K. Nakakuki, "First-order kinetic model of Alzheimer's β -amyloid fibril extension <i>in vitro</i> ," <i>Laboratory investigation</i> , 74(2):374-383 (1996)
	CO*	Niwano et al., "Inhibitory action of amyloid precursor protein against human Hageman factor (factor XII)," <i>J. Lab. Clin. Med.</i> 125:251-6 (1995)
	CP*	Pardridge et al. "Amyloid Angiopathy of Alzheimer's Disease: Amino Acid Composition and Partial Sequence of a 4,200-Dalton Peptid Isolated from Cortical Microvessels," <i>Journal of Neurochemistry</i> , 49(5): 1394-1401, (1987)
	CPQ*	Pike et al. "In Vitro Aging of β -Amyloid Protein Cause Peptide Aggregation and Neurotoxicity," <i>Brain Research</i> , 563:311-314, (1991)
	CR*	Pike et al. "Structure-Activity Analyses of β -Amyloid Peptides: Contributions of the β 25-35 Region to Aggregation and Neurotoxicity," <i>Journal of Neurochemistry</i> , 64(1): 253-265, (1995)
	CS*	Pollanen et al., "Pathology and Biology of the Lewy Body," <i>Journal of Neuropathology and Experimental Neurology</i> , 52(3):183-191 (1993)
	CT*	Polymeropoulos et al., "Mutation in the alpha-synuclein gene identified in families with parkinson's disease," <i>Science</i> 276:2045-2047 (1997)
	CU*	Ponte et al. "A New A4 Amyloid mRNA Contains a Domain Homologous to Serine Proteinase Inhibitors," <i>Nature</i> , 311:525-527, (1988)
	CV*	Puchtler, H. et al., "On the binding of congo red by amyloid," <i>Journal of Histochemistry and Cytochemistry</i> 10:355-364 (1962)
	CW*	Rogers et al., "Long-term efficacy and safety of donepezil in the treatment of Alzheimer's disease: an interim analysis of the results of a US multicentre open label extension study", <i>Eur. Neuropsychopharmacol.</i> , 8:67-75 (1998)

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